BIOMET

K061681

510(k) Summary

Preparation Date: June 9, 2006

OCT 19 2006

Applicant/Sponsor: Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Lester F. Padilla

Proprietary Name: Repicci II® Metal Back Inlay Unicompartmental Tibial Bearing Component

Common Name: Tibial component for uni-condylar knee replacement

Classification Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3530)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
1. Repicci II® Unicondylar Knee (K971938)
2. Repicci II® Unicondylar Knee All Poly Tibial Components (K980665)

Device Description:
The Repicci II® Metal Back Inlay Unicompartmental Tibial Component is a tibial component comprised of ultra-high molecular polyethylene (UHMWPE), with a thin corrugated metal plate molded into the inferior surface of the device. The tibial components are available in six profiles and two thicknesses and is intended for cemented fixation.

Intended Use:

Partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. The devices covered in this 510(k) are intended to be used with Repicci Femoral component. The device is intended to be used with bone cement.

Summary of Technologies: The technological characteristics (material, design, sizing, and indications) of the Repicci II® Metal Back Inlay Unicompartmental Tibial Bearing Component are similar or identical to the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Biomet, Inc.
% Lester F. Padilla, RAC
Regulatory Affairs Associate
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46581

OCT 19 2006

Re: K061681
Trade/Device Name: Repicci II® Metal Back Inlay Unicompartmental Tibial Bearing Component
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY
Dated: September 18, 2006
Received: September 21, 2006

Dear Mr. Padilla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: Repicci II® Metal Back Inlay Unicompartmental Tibial Bearing Component

Indications for Use:

Partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

The devices covered in this 510(k) are intended to be used with Repicci Femoral component.

The device is intended to be used with bone cement.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __NO___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061641